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09/775,925	02/01/2001	Ralf M. Luche	200125.420	3867

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SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 6300
SEATTLE, WA 98104-7092

EXAMINER	
SAIDHA, TEKCHAND	

ART UNIT	PAPER NUMBER
1652	10

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
09/775925	Luche et al.	
Examiner	Group Art Unit	
T. Sadhna	1652	10

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address---

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

X Responsive to communication(s) filed on 4/21/03

This action is **FINAL.**

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

X Claim(s) 1-98 ~~is~~/are pending in the application.

Of the above claim(s) 1&15-98 ~~is~~/are withdrawn from consideration.

Claim(s) ____ is/are allowed.

X Claim(s) 2-14 ~~is~~/are rejected.

Claim(s) ____ is/are objected to.

Claim(s) ____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The proposed drawing correction, filed on ____ is approved disapproved.

The drawing(s) filed on ____ is/are objected to by the Examiner.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number)

received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received:

Attachment(s)

Notice of Draftsperson s Patent Drawing Review, PTO-948 Other

Office Action Summary

U.S. Patent and Trademark Office

PTO-326

DETAILED ACTION

1. ***Election***

Applicant's election of Group II (claims 2-9 & 14) ***without traverse*** in Paper No. 9, filed 4.21.03 is acknowledged. Claims 10-13 are rejoined with the elected group II claims as belonging to the same group, which were inadvertently restricted to group III.

Claims 1 & 15-98 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Claims 2-14 are pending and under consideration in this examination.

3. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

4. ***Claim Objections***

Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 6 depends on non-elected claim, therefore this objection. Compliance with the above suggestion(s) will overcome this objection.

5. ***35 U.S.C. § 112, first paragraph (Written Description)***

skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claims 2-6 & 8-14 recite and encompass 'an isolated polynucleotide that encodes 10 or 15 consecutive amino acids (claims 2-3) or an antisense polynucleotide comprising 15 consecutive nucleotide (claim 10) or where the expression vector/host cell comprises the encoding polynucleotide of claim 2 or 3 (claims 4-5)...'. No functionality is associated with the fragments of 10 or 15 contiguous amino acids of SEQ OD Nos. 2 encoded by SEQ ID No. 1 as disclosed in the specification. Further, no description is provided of the use of these fragments or in the recombinant construction of vector, host cell and the method of making a polypeptide having DSP-12 or phosphatase activity. Even if such fragments of the polypeptides can be recombinantly expressed (claim 14), without the fragment being enzymatically active, it would be impossible to isolate such polypeptide fragments (without being active) from among mixture of polypeptides. The specification discloses only the full length nucleotides sequences of SEQ ID Nos. 1 encoding a human phosphatase of SEQ ID NO : 2 as the species of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. No function is associated with the fragments. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The specification also fails to describe additional representative species of these phosphatases

Similarly, no specific hybridization conditions are recited (claims 11-13) other than the wash conditions compared to the moderately stringent conditions described in the specification (page 11, lines 1-11). The definition of "stringency" as it pertains to hybridization conditions is subject to interpretation and is different from laboratory to laboratory. Therefore, without a clear and explicit recitation of what conditions are meant to be included by the term "hybridizes", and without a clear and explicit recitation of the conditions (for example, moderately stringent as defined and recited in the claims) which were actually used by Applicants in isolating polynucleotides which hybridize to SEQ ID NO: X, the skilled artisan cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Therefore, the written description requirement is not satisfied.

6. ***35 U.S.C. § 112, first paragraph (enablement)***

Claims 2-6 & 8-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide of SEQ ID NO : 1 encoding a full-length DSP-12 polypeptide of SEQ ID NO: 2, corresponding antisense molecule, vector, host cell and the method of making the recombinant DSP-12 polypeptide, does not reasonably provide enablement for any polynucleotide encoding a DSP-12 polypeptide having 50% identity to SEQ ID NO: 2 (claim 6), or a polynucleotide (or antisense) encoding a fragment of SEQ ID NO : 2 which is 10 or 15 contiguous amino acids in length and use such sequences in vector & host cell constructs

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

The scope of the claims do not commensurate with the enablement provided by the disclosure with regard to the extremely large number of nucleic acid molecules which may or may not encode the desired dual specificity phosphatases broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence (in order to making the necessary changes in the encoding DNA sequence(s)) and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide sequence of SEQ ID NO : 1 encoding the amino acid sequence of human DSP-11 of SEQ ID NO : 2.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance

The specification does not support the broad scope of the claims which encompass all modifications of any nucleic acid encoding DSP-12 with 50% identity [or 50% modification by deletion, addition or substitution] to SEQ ID No. 1 where the nucleic acid molecule(s) may comprise a fragment 30 or 45 bases form SEQ ID NO : 1 encoding 10 or 15 mers of SEQ ID Nos: 2, because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting phosphatase (DSP-12) activity; (B) the general tolerance of DSP-12 to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any DSP-12 from any source(s) with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

With regard to claims 11-13, directed to a polynucleotide sequence that hybridizes to the disclosed sequence of SEQ ID NO : 1, Applicants have not sufficiently defined the conditions under which the hybridizations are to take place (claim 11) or if stringent conditions are 'low', 'medium or moderate' or 'high'. Nucleic acid hybridization assays are extremely sensitive to the conditions in which they are performed. The buffer composition, pH, temperature, length of time, salt concentrations, quality and source of template nucleic acid, are all variables which determine the reproducibility of a given hybridization experiment. Given the unpredictability of the art and the nature of hybridization experiments in general, it is not sufficient to merely cite hybridization without

definition of stringency as it pertains to hybridization conditions is subject to interpretation and is different from laboratory to laboratory.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any polypeptide [phospholipase] with an enormous number of amino acid modifications of the of SEQ ID NOS: 2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of all the DSP-12 polypeptides having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Including in the claims the exact nature of the hybridization conditions used to isolate the claimed polynucleotides would aid in overcoming this portion of the rejection.

7. Claim 7 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and drawn to full length sequence(s).

8. Claims 6-10 & 14 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

indefinite. The first use of an uncommon abbreviation in a claim must always be defined, which may be abbreviated in the subsequent claims.

Claims 7-10 are included in the rejection for failing to correct the defect present in the base claim(s).

9. ***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-3 & 10 are rejected under 35 U.S.C. 102(a) as being anticipated by Accession No. AL121363 (created 25 September, 1999) or Accession No. AL121364 (created 25 September, 1999).

Accession Nos. AL121363, a nucleotide sequence having nucleotide bases 1-339, which are exact and contiguous match to Applicants' SEQ ID NO : 1 bases 911-1249. Similarly, Accession Nos. AL121364/c, a nucleotide sequence having nucleotide bases 550-8 (complementary), which are exact and contiguous match to Applicants' SEQ ID NO : 1 nucleotide bases 1320-1865. Since,

nucleotides which would inherently encode 110-180 contiguous amino acids, the reference teaches all the claim limitations and therefore this anticipation rejection.

10. No claim is allowed.

11. ***Allowable subject matter***

Claims drawn to full length sequences or that reciting the sequences and the hybridization conditions (stringency), as taught in the instant specification, will be favorably considered for allowance.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha (Ph.D.) whose telephone number is (703) 305-6595. The examiner can normally be reached on Monday-Friday from 8:15 am to 4:45 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy, can be reached at (703) 308-3804. The fax phone number for this Group in the Technology Center is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Tekchand Saidha
Primary Examiner, Art Unit 1652
May 29, 2003